UNITED STATES PATENT AND TRADEMARK OFFICE

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10/765,547	01/26/2004	Seung-Hak Choi	YPL-0077	1634

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

-- *The MAILING DATE of this communication appears on the cover sheet with the correspondence address* --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE _3_ MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.
- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on _23 April 2008_.

2a)☒ This action is **FINAL**.   2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) _1-14_ is/are pending in the application.

    4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) _1-14_ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

    Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

    Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

    a)☐ All   b)☐ Some * c)☐ None of:

      1.☐ Certified copies of the priority documents have been received.

      2.☐ Certified copies of the priority documents have been received in Application No. _____.

      3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

    * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1)☐ Notice of References Cited (PTO-892)

2)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3)☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.

4)☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.

5)☐ Notice of Informal Patent Application

6)☐ Other: _____.

DETAILED ACTION

Amendments/Response

Applicants' amendment and request for reconsideration filed 4/23/08 are acknowledged and the amendment is entered.

Claims 1-14 are currently pending and under consideration.

Applicant's arguments in response to the previous Office action mailed 4/17/07 have been fully considered but they are not deemed to be fully persuasive. The following rejections and/or objections are either reiterated from the previous Office action or newly applied but necessitated by applicant's amendments, and constitute the complete set presently being applied to the instant application. Rejections and/or objections set forth in the previous Office action but not reiterated herein are hereby withdrawn.

Specifically, the rejections of claims 1-8 under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter and under 35 U.S.C. 112 , second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention set forth in the previous Office action are hereby withdrawn in view of the amendment filed 4/23/08.

Claim Rejections-35 USC § 112

The following is a quotation of the **second** paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-14 are rejected under 35 U.S.C. 112 , second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is amended to recite "downloading an analysis algorithm corresponding to the biochip from the analysis algorithm database." The metes and bounds of the limitation are not clear because it is unclear what is meant by "corresponding." The term is not defined in the specification and one skilled in the art would not know what criteria to be based upon to download the algorithm. For example, anything about the biochip might be based upon for the downloading, e.g. the name, the manufacture, the date of production, the specific features contained, etc. of the biochip.

Claims 9 and 12 are rejected for the same reason.

Claim 6 recites the system of claim 1, "wherein the client comprises ...." The term "the client" lacks sufficient antecedent basis because a client is not recited in claim 1, and it is unclear whether it refers to the client system in claim 1.

Claims 7, 10, 11 are rejected for the same reason as that set forth above for claim 6 as the phrase "the client" recited therein lack clear antecedent basis.

All claims depending from independent claims 1, 9 or 12 are rejected as they do not contain limitations that clarify the unclearness of the independent claims set forth above.

Claim Rejections-35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the

basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-14 are rejected under 35 U.S.C. § 102(b) as being anticipated by Osborne et al.

(IDS document: Artificial Intelligence System for Genetic Analysis, WO 01/16860 A2, March 8,

2001).

In light of the indefiniteness of the claims set forth above, the art is being applied to the

best interpretation of the claims as written.

The claims are amended to be drawn to a server-client network system for genotyping

analysis on a target sample. The network comprises a server including an analysis algorithm

database for the genotyping analysis and a client system communicatively coupled to the server,

which receives the results of a biochip test on the target sample, downloads an analysis algorithm

corresponding to the chip, perform the genotyping analysis and stores the results in the client

system.

With regard to at least independent claims 1 and 12, Osborne et al. disclose a network

system and a method for genetic analysis. The network system comprises a server that includes

multiple databases required for the genetic analysis, which are provided to client that receives the

results of a microarray analysis and performs the genetic analysis. See at least Fig. 1. and pages

4-5. The genetic analyses include analysis of genomic mutations (see page 12, lines 30-31),

which is interpreted as a type of genotyping. Osborne et al. disclose that the system comprises

central data processing facilities and user facilities and that "each user facility may include an

optical scanning system to collect hybridization signals from a nucleic acid array, an image

processing system to convert the optical data into a set of hybridization parameters, a connection

to a data network, and a user interface to display, manipulate, search, and analyzed hybridization

information." See page 5. The system comprises various types of users at different tiers including

remote users/local users, web users/internet users, diagnostic users including diagnostic master

users, and browser users (see pages 10-12), any and all of which is interpreted as being part of

the client system as recited in the instant claims. Since the user facilities (interpreted as client)

and the central data processing facilities (interpreted as server) comprising the databases are

linked by encrypted network connections (see page 5), it is interpreted that the databases in the

server are provided to the client and that the client system is communicatively coupled to the

server.

> Furthermore, Osborne et al. state on page 12:
>
> There are two categories of diagnostic users, such as "diagnostic master users" and
> "diagnostic users". Accounts for diagnostic master users are authorized and correspond to
> the user sites where the systems are deployed. These diagnostic master users are allowed
> to authorize accounts for diagnostic users. For clinical applications, diagnostic users
> correspond to the individuals that have been tested. For research and development
> applications, diagnostic master users can designate either individual chip test results or
> groups of chips as a single diagnostic user, wherein this option lies with the diagnostic
> master users in order to meet their testing and analysis needs. Diagnosis processing is a
> key part of the artificial intelligence system. The diagnosis processing for clinical
> applications may be different from that of research and development applications.
> Diagnosis processing for clinical applications implements a rules based analysis
> application which utilizes a database set of rules and results. Diagnosis processing
> thereby determines which conditions apply to the various combinations of gene
> expression levels and personal medical history.

The accounts authorized to diagnostic users are also interpreted as part of the client

system as the accounts correspond to the user sites. Additionally, this statement clearly indicates

that for a diagnostic user, i.e. client, to perform the diagnosis processing, the user first receives

the systems because they "are deployed," and the system includes databases of rules, etc., which

are interpreted as analysis algorithms.

With regard to claims 2 and 13, the databases in the server disclosed by Osborne include

database for chip ID and pattern/lay-out, analysis algorithm and a quality control database. See at

least Fig. 1 and pages 5-7, 10, 12-14, and 27. See also pages 19-22 for rules/algorithm for

analysis in the system.

With regard to claims 3-4, the server of the system by Osborne et al. comprises database

that is built up from statistical data for the results of test on a number of patients and references

samples using microarrays. Osborne et al. disclose that the database server stores hybridization

profiles, patient profiles, reference information, clinical information associated with

hybridization profiles, and statistical summaries. See page 5. Osborne et al. further disclose that

"hybridization profiles collected by remote and/or local facilities include clinical observations or

other information associated with each profile, and the profile with associated observations is

added to the central database." See page 6. Osborne et al. also state that "the databases of the

instant invention continually mature and develop into more and more complex systems as

information from public and private sources continues to be added to the existing database." See

pages 13 and 15. Thus, the databases are being built up while the users use the system.

With regard to claim 5, in the system disclosed by Osborne et al., the users/clients

comprise optical scanning system and identifier recognizer. See at least Fig. 1 and pages 11 and

16.

With regard to claims 6-8 and 14, which include limitations that the client comprises an

engine for performing a series of logical functions, in the system disclosed by Osborne et al., the

client comprises an engine or means for performing a function of detecting the identifier of the

biochip (see Fig. 1 and the "application ID on at least page 16, array ID and array location ID on at least pages 26-27, and sample ID, patient ID, etc. on pages 28-29). Client can select and download data/database based on application ID, etc., and perform genotyping analysis. See the diagnostic architecture listed on pages 16-18. Furthermore, with regard to claim 8, the method of Osborne et al. allows client to perform the genetic analysis including reading results via scanning system, (see pages 16-18), linking results with spot position information of the chip, etc. (see pages 13-14, where the database queries include chip ID genetic pattern, pattern match, result output, etc. and page 15). Users can perform functions such as correlating they hybridization signals of one or more probes and creating test hypothesis relating to a particular pathological or physiological condition, using the server databases to search, correlate, manipulate and display existing data, etc. See page 15.

With regard to claims 9-11, which are drawn to computer readable medium comprising computer executable instructions for executing the method steps and functions performed by the system above, given that the system for performing the functions and method steps as set forth above is a web-based computer systems including server and client, it would be readily recognized by one skilled in the art that the system inherently comprises computer readable medium containing computer executable instructions for performing the functions.

Applicant's arguments filed 4/23/08 have been fully considered but they are not found persuasive.

Applicant argues that Osborne et al. do not disclose that analysis algorithms are stored in the server, that the client system downloads an analysis algorithm corresponding to the chip from the server and performs the genotyping analysis. See page 13 of 14.

This is not found persuasive.

Based on Osborne et al.'s statement on page 12, which is cited above, for a diagnostic user, i.e. client, to perform the diagnosis processing, the user first receives the systems from the server because they "are deployed," and the system includes databases of rules, etc., which are interpreted as analysis algorithms. The fact that the system with the databases have to be deployed, which is interpreted as downloading on the user's perspective, in order for a user to perform the analysis indicates that the databases are stored in the server.

This argument was presented in the previous Office action mailed 4/17/07 on page 7 in response to a similar argument by applicant filed on 1/22/07, but applicant did not argue against the examiner's position in the response filed 4/23/08.

Conclusion

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicants are reminded of the extension of time policy as set forth in 37 C.F.R. §1.136 (a). A shortened statutory period for response to this final action is set to expire three months from the date of this action. In the event a first response is filed within two months of the mailing date of this final action and the advisory action is not mailed until after the end of the three-month shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 C.F.R. §1.136 (a) will be

calculated from the mailing date of the advisory action. In no event, however, will the statutory

period for reply expire later than six months from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shubo (Joe) Zhou, whose telephone number is 571-272-0724. The examiner can normally be reached Monday-Friday from 8 A.M. to 4 P.M. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marjorie Moran, can be reached on 571-272-0720. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

/Shubo (Joe) Zhou/

SHUBO (JOE) ZHOU, PH.D.

PRIMARY EXAMINER